IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC, AND QUALICAPS CO., LTD.	§	
	§	
	§	Case No. 2:15-cv-01471-JRG-RSP (Lead)
v.	§	Case No. 2:17-cv-00343-JRG-RSP (Member)
	§	
TEVA PHARMACEUTICALS USA, INC.	§	

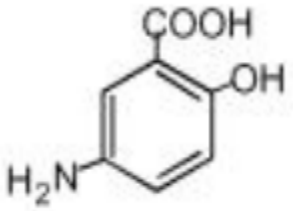
MYLAN PHARMACEUTICALS, INC., MYLAN LABORATORIES LIMITED, MYLAN, INC.	§	
	§	Case No. 2:15-cv-01740-JRG-RSP (Member)
	§	

REPORT AND RECOMMENDATION

This patent infringement action arises from Abbreviated New Drug Applications (ANDAs) filed by Teva Pharmaceuticals USA, Inc. ("Teva") and the Mylan defendants ("Mylan") to market a generic version of the ulcerative colitis drug sold by Allergan Sales, LLC ("Allergan") under the brand name Delzicol. The dispute does not concern the Delzicol drug, but rather concerns the capsule that holds the drug and the patent covering the capsule. The dispute is whether the capsule that Mylan and Teva would market upon regulatory approval falls within the scope of the asserted claims, which are directed only to a capsule. Mylan and Teva move for summary judgment of noninfringement, each contending that their proposed generic products would not include at least one element of the asserted claims. Because the accused capsules are not formed from a film composition comprising a "gelling agent," as the asserted claims require, summary judgment must be granted.

BACKGROUND

The parties to this lawsuit sell or are seeking approval to sell a drug product that includes mesalamine, a compound useful for treating ulcerative colitis.[1] Mesalamine is also known by its chemical name, 5-amino-2-hydroxybenzoic acid, and it is represented by the following structural formula:[2]



A division of the Warner Chilcott Company, LLC ("Warner Chilcott"), which is now owned by Allergan, has maintained brand exclusivity for a 400 mg mesalamine tablet since 1992, first with its branded Asacol product (now discontinued), and more recently with its branded Delzicol product. Warner Chilcott's Asacol New Drug Application (NDA) was approved on January 31, 1992.[3] Two Orange Book-listed patents covered Asacol, U.S. Patent No. 5,541,170 ("the '170 patent"), filed March 10, 1995, and U.S. Patent No. 5,541,171 ("the '171 patent"), filed May 23, 1995. Both patents describe and claim a pharmaceutical composition suitable for orally administering mesalamine. Proctor & Gamble's branded pharmaceutical division (later acquired by Warner Chilcott) obtained a license to these patents and listed them on the label for the first

[1] Relevant statutory and regulatory background is described in a previous Order of the Court. *See* Dkt. 197.

[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/019651s023lbl.pdf.

[3] https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=019651

delayed-release 400 mg mesalamine tablet for oral administration, which was marketed and sold as Asacol until 2013. *Id.*

I. Warner Chilcott's Negotiations with Qualicaps and Asacol Reformulation

The '170 and '171 patents were scheduled to expire in July 2013. *See* Dkt. 153-2 at QCDEZ_00001322. Admissible evidence suggests that the impending patent expiration prompted Warner Chilcott to begin negotiations with Qualicaps Co., LTD. ("Qualicaps") sometime in 2012. *See* Dkt. 153-2.[4] Warner Chilcott's plan, according to a Qualicaps employee, was to change the approved branded dosage form from a tablet to a tablet within a hydroxypropyl methyl cellulose capsule. *Id.* at QCDELZ_0001322. Qualicaps happened to be the owner of U.S. Patent No. 6,649,180 ("the '180 patent"), which claimed a hydroxypropyl methyl cellulose capsule, and which was not scheduled to expire until April 13, 2020. *See* '180 patent, Dkt. 1-2, 35 U.S.C. § 154(a)(2).

According to documents from Qualicaps, Warner Chilcott was interested in listing the '180 patent in the Orange Book for Asacol. *Id.* at QCDELZ_00001322. As a Qualicaps employee explained,

> By listing our patent (with protection until 2019) any generic company who wishes to launch a generic version must notify [Warner Chilcott] of their intention [and] technical plans. [Warner Chilcott] will then have time to launch a defence [sic] against the generic launch. [Warner Chilcott] believe[s] this defence [sic] will be hard for them to win, but will "buy them between 3-30 months" of market protection as the defence process takes time. *Id.*

[4] The Court ruled at the pretrial conference that relevant emails from a Qualicaps employee summarizing and relaying communications with Warner Chilcott were admissible under Fed. R. Evid. 801(d)(2). Neither the statements made by the Qualicaps employee nor the internal statements by Warner Chilcott are hearsay because both statements were made by an agent or employee of a party who was or is now a plaintiff in this lawsuit. This evidence, however, is provided only for background and does not affect the Court's summary judgment recommendation.

Id. Qualicaps saw the risk in exposing the ’180 patent to challenge, but based on assurances from Warner Chilcott, Qualicaps characterized the risk as low because it was easier for a generic manufacturer to “work around” the Orange Book listing rather than “tackle the patent.” *Id.* at QCDELZ_00001324. Warner Chilcott’s negotiations with Qualicaps were ultimately successful.

After obtaining a license to the ’180 patent, Warner Chilcott reformulated its Asacol product and filed the NDA for Delzicol. Comp. ¶ 28, Dkt. 1. The Delzicol NDA identified one patent for Orange Book listing—the ’180 patent. Although Warner Chilcott’s plans succeeded, the change in formulation and other maneuvers prompted an antitrust lawsuit in the District of Massachusetts. *See, e.g.*, *In re Asacol Antitrust Litig.*, No. 15-cv-12730-DJC, 2017 WL 588288 (D. Mass. Feb. 10, 2017). Warner Chilcott and now Allergan maintain that the switch was not for an improper purpose but rather to respond to concerns by the Food and Drug Administration (FDA) about dibuytyl phthalate (DBP), an excipient present in Warner Chilcott’s original Asacol product. *See* Dkt. 159-5 (Warner Chilcott letter to FDA regarding Asacol NDA).

II. The ’180 Patent

Unlike the ’170 and ’171 patents—the patents covering Warner Chilcott’s original Asacol product—the ’180 patent does not claim or describe a composition including mesalamine. Neither mesalamine nor any ulcerative colitis drug is mentioned in the ’180 patent. The ’180 patent claims “[a] hard capsule formed of a film composition” comprising, among other things, “hydroxypropyl methyl cellulose [HPMC]” with limited amounts of aliphatic propoxyl and methoxy groups. *See* ’180 patent, claim 1. According to the patent, by limiting cellulosic alkyl or hydroxyalkyl groups in the film, enough hydrophilic hydroxyl groups remain in the HPMC to ensure the film holds enough water. *Id.* at 2:41-49. This prevents potassium or calcium from precipitating from the film, which ordinarily would cause the capsule to be “unpleasant to look at.” *Id.* at 2:41-49; 1:53-56,

2:1-6. As far as the patent reveals, the sole purpose of the film described in the '180 patent is to "maintain[] [a capsule with] a favorable outer appearance during long-term storage." *Id.* at 2:9-15.[5]

A. "Gelling Agent"

The claim element most relevant to Teva and Mylan's motions for summary judgment is the "gelling agent" limitation. Claim 1 of the '180 patent, the only independent claim, recites in its entirety:

> A hard capsule formed of a film composition comprising a hydroxypropyl methyl cellulose as a base, *a gelling agent*, and a gelling aid, wherein said hydroxypropyl methyl cellulose has a content of hydroxypropoxyl groups of at least 4% by weight of the hydroxypropyl methyl cellulose and a content of methoxyl groups and hydroxypropoxyl groups combined of 23 to 37.6% by weight of the hydroxypropyl methyl cellulose.

Id. at 6:38-46 (emphasis added). The '180 patent describes a variety of gelling agents that can be used to gel the film composition:

> The gelling agent used may be selected from among, for example, carrageenan, tamarind seed polysaccharide, pectin, curdlan, furcellaran, gellan gum, and mixtures thereof. Of these, carrageenan is especially preferred because it has a high gel strength and exhibits good gelling properties in the co-presence of a specific ion so that it may achieve effective gelation even when added in small amounts. While there are known three types: kappa-carrageenan or iota-carrageenan and lambda-carrageenan, the invention recommends to use kappa-carrageenan and/or iota-carrageenan which have a good gelation ability.

'180 patent at 3:60-4:3. Like all of the gelling agents described in the specification, the preferred gelling agent, carrageenan, is a hydrocolloid. *See* Dkt. 100-2 ¶ 39.

[5] The PTAB instituted inter partes review (IPR) of the asserted claims of the '180 patent on May 16, 2017, finding "a reasonable likelihood" that the claims are invalid. *See* IPR2017-00203, Dkt. 10. No party has requested a stay pending IPR.

The hard capsule recited in the claims can be prepared by "any well-known method," according to the patent. *See, e.g.*, '180 patent at 4:54-55. But the example described in the specification involves a dipping method in which solid pins (or templates) defining the interior volume of a capsule are dipped into the film composition solution, and as the film composition gels, a hard film forms on the pin, the hard film is then cut into two pieces, and the pieces are removed from the pin. *See, e.g.*, '180 patent at 4:54-5:17. Complementary pieces are then mated to construct the hard capsule with a hollow interior in the shape of the pin. *Id.* at 5:3-4. The process involves water but only as a solvent to dissolve the HPMC, gelling agent, gelling aid, and other optional additives. *Id.* at 4:59-64.

B. Construction of "Gelling Agent"

During claim construction, Plaintiffs proposed that "gelling agent" did not need a construction, but that if a construction was necessary, the term should be construed as "[a]n agent that can gel a film composition comprising hydroxypropyl methyl cellulose as a base." *See* Claim Construction Opinion & Order at 11, Dkt. 191. Teva and Mylan were concerned that Plaintiffs would contend that the water used in making their generic capsule could qualify as the "gelling agent" by itself, and thus Teva and Mylan sought to limit the term to the gelling agents disclosed in the specification. *See id.* Teva and Mylan therefore proposed that "gelling agent" be construed under 35 U.S.C. § 112, ¶ 6 as a means-plus-function term, i.e., a substance that increases the amount of gelation corresponding to the structure of "carrageenan, tamarind seed polysaccharide, pectin, curdlin, furcellaran, gellan gum, and mixtures thereof." *Id.*

The Court rejected Teva and Mylan's proposal to construe the term under § 112, ¶ 6 because the term lacked the word "means" and because a person of ordinary skill in the art would understand the term by its function. *Id.* at 11-14. The more difficult questions were what the scope

of the term should be and whether the parties' dispute about water being a "gelling agent" was an issue that should be addressed through claim construction. The Court saw merit in two approaches.

First, even if not construed under § 112, ¶ 6, "gelling agent" could be construed to correspond to the class of hydrocolloid structures described in the specification and their equivalents. *Id.* at 13. The Court explained that this approach would not be violating the rule against importing embodiments into the claims but rather, borrowing from the familiar *noscitur a sociis* canon, would limit "gelling agent" to the general type of substances disclosed in the specification and their equivalents. *Id.* If so limited, water could not be considered a "gelling agent" as a matter of law.

Second, the Court saw merit in construing the term according to its function in light of evidence that a person of ordinary skill in the art would understand the scope of the term in light of the gelling function. Ultimately, the Court adopted such a construction because limiting the claims to the class of hydrocolloid structures disclosed in the specification seemed equivalent to construing the term, improperly in the Court's view, under § 112, ¶ 6. *See id.* 13. The Court therefore construed "gelling agent" according to its plain and ordinary meaning, which is a "substance that gels the film composition." *Id.* at 15.

A third approach that was not as apparent at the time was to resolve the dispute regarding the "gelling agent" term at claim construction and hold as a matter of law that water could not be a "gelling agent." The problem, however, was that Mylan and Teva did not advocate for such an approach—Mylan and Teva's proposal would have accomplished the same result but the proposal to construe the term under § 112, ¶ 6 went too far, and as a result, was not credible. Mylan and Teva's approach was nevertheless understandable because the Court is reluctant at the claim construction phase to carve out a defendant's accused product with a negative claim construction

that says, in effect, "this product does not infringe." As the Federal Circuit has cautioned, "[a] claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, not in light of the accused device." *SRI Int'l v. Matsushita Electric Corp. of America*, 775 F.2d 1107, 1118 (Fed. Cir. 1985). The dispute about whether water could be a "gelling agent" seemed, at least at the time, to be more of an infringement dispute than a claim construction dispute. *See* Dkt. 191 at 14.

III. Mylan and Teva's Generic Products

Mylan and Teva's generic mesalamine products include a mesalamine tablet (or tablets) within an HPMC capsule.[6] The capsule used for the generic products is sold under the brand name Vcaps Plus. While the Vcaps Plus capsules are made from gelled HPMC, they are not made in the same manner described by the '180 patent. Rather, the Vcaps Plus capsules are made by a process known as thermal gelation, or thermogelation. As Plaintiffs' expert, Dr. Roland Bodmeier, explains, Vcaps Plus capsules are made by dipping a heated pin into an aqueous solution of HPMC, and when the pins are withdrawn, the HPMC forms a film. *See, e.g.* Bodmeier Rep. ¶ 67, Dkt. 213-13.

This thermogelation process takes advantage of the intrinsic gelling properties of HPMC. As all of the evidence supporting Dr. Bodmeier's opinion indicates, when HPMC is dissolved in a solution of water at room temperature or below, water forms a cage-like structure around the hydrophobic (water-repellant) HPMC groups, such as the methyl substituents. *See* Nitis Sarkar Article, Dkt. 222-3, at 195. When the aqueous solution of HPMC is heated, the water structure breaks down, owing to an increase in entropy (disorder), which allows the hydrophobic HPMC

[6] See Dkt. 213-10 at MYL_MESA_000131-139; Dkt. 213-11 at MYL_MESA_00001279; Dkt.214-6 at TEVA_MS_0088744 at -750; Dkt. 214-7 at TEVA_MS_0088724 at -725.

groups to interact causing the HPMC to gel and precipitate. *See id.* In other words, heat causes the water to get out of the HPMC's way so that the HPMC can gel on its own. *See id.*

Although the HPMC in the Vcaps Plus capsule ultimately becomes gelled, Mylan and Teva's process does not involve the use of a hydrocolloid-like gelling agent, such as those described by the '180 patent, or any similar additive for that matter. Mylan and Teva explain that this was by design. The product brochure for the Vcaps Plus capsules explains that HPMC capsules were "originally formulated with a secondary gelling agent." Dkt. 213-15 at 2. The secondary gelling agent, however, was found to "delay dissolution in some circumstances and lead to unwanted issues during product development." *Id.* Thus, the point of developing the Vcaps Plus capsule was to avoid "using a gelling agent," and thus "a thermal gelling process was selected that eliminated the need to use a gelling agent and salts as co-gelling agents." *Id.* at 4.

IV. Allergen's Infringement Contention

Mylan and Teva's ANDA seeking approval for a mesalamine product inside the Vcaps Plus capsule prompted Allergan to file lawsuits under the Hatch-Waxman Act. Although Teva contends that the '180 patent should never have been listed in the Orange Book because it does not claim or even relate to mesalamine, *see, e.g.*, Dkt. 216, the listing required Mylan and Teva to notify Warner Chilcott (the original NDA holder, now Allergan) of the requisite Paragraph IV certification, which allowed Allergan to take advantage of the 30-month regulatory stay. *See* Dkt. 191 at 1-9. Mylan and Teva are unable to market their generic products until this stay has expired, or until a district court renders a judgment of noninfringement or invalidity. *See id.*

With respect to the "gelling agent" limitation, Allergan contends that water, or heated water more specifically, qualifies as the "gelling agent." *See, e.g.*, Dkt. 221. Allergan has not come forward with any direct testing evidence that water plays any role in the thermogelation process

used to the make the Vcaps Plus capsules. Rather, Allergan relies on literature references, such as the Sarkar article described above, explaining how the HPMC thermogelation process occurs in water. *See* Bodmeier Rep. ¶¶ 29-32, Dkt. 222-3. On the basis of such literature references, Dr. Bodmeier opines that water is a "gelling agent" because "at elevated temperatures (i.e., above room temperature)," water "increases the gelation of HPMC." *Id.* ¶ 31. Thus, Allergan's theory is that because the literature has recognized heated water to play a role in the thermogelation of HPMC, heated water is necessarily a "gelling agent." *Id.* ¶¶ 29-32.

Mylan and Teva contend that summary judgment of noninfringement must be granted because the Vcaps Plus capsule was not made with a "substance that gels the film composition," as the Court's claim construction requires. *See* Dkts. 213 & 214.

DISCUSSION

Summary judgment must be granted when there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "A genuine issue of material fact exists 'if the evidence is such that a reasonable jury could return a verdict for the non-moving party.'" *Crawford v. Formosa Plastics Corp., La.*, 234 F.3d 899, 902 (5th Cir. 2000) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The court must consider evidence in the record in the light most favorable to the non-moving party and draw all reasonable inferences in favor of that party. *Thorson v. Epps*, 701 F.3d 444, 445 (5th Cir. 2012). The moving party must identify the portions of the record that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once a party has made that showing, the non-moving party bears the burden of establishing otherwise. *Geiserman v. MacDonald*, 893 F.2d 787, 793 (5th Cir. 1990) (citing *Celotex*, 477 U.S. at 323). The non-moving party cannot "rest upon mere allegations or denials" in the pleadings, but "must set forth specific

facts showing there is a genuine issue for trial." *Liberty Lobby*, 477 U.S. at 248. Thus, summary judgment "is appropriate if the non-movant 'fails to make a showing sufficient to establish the existence of an element essential to that party's case.'" *Bluebonnet Hotel Ventures, LLC v. Wells Fargo Bank, N.A.*, 754 F.3d 272, 276 (5th Cir. 2014) (quoting *Celotex*, 477 U.S. at 322).

I. Clarifying Claim Construction

What initially appeared as an infringement dispute on the original claim construction record now appears more like a claim construction dispute. Although the Court does not see a basis to limit the term "gelling agent" to the class of hydrocolloid polymers described by the '180 patent, there is a basis in the intrinsic record (alone) to conclude as a matter of law that water is not a "gelling agent." Water is mentioned in the specification 21 times, but never as a "gelling agent" or even as a component of the film composition that aids in the gelation process at all. Rather, water is mentioned in two contexts—(1) in terms of residual "water content" present in the capsule, *see, e.g.*, '180 patent at 1:57-67, and (2) as a solvent used to dissolve the HPMC, gelling agent, gelling aid, and other optional additives during the capsule forming process, *see, e.g.*, *id.* at 4:59-64.

It follows that, although water may be used during the capsule-forming process, it is not the "gelling agent" as the inventors understood that term. Although not necessarily limited to hydrocolloids, water is nothing like the example gelling agents disclosed in the specification, such as carrageenan, for example. *See* '180 patent at 3:60-66. The specification strongly suggests that the gelling agent is a solid, or at least a substance conventionally measured "by weight." *See id.* at 4:4-17. Even in general terms, the inventors describe the amount of "gelling agent" to be used in terms of "parts by weight of the cellulose ether." *See id.* at 4:10-12. More important, the fact that the inventors contemplated the presence of water in the process but failed to call water out as a "gelling agent" is telling. "[T]he correct construction" is always the construction that "stays true

to the claim language *and most naturally aligns with the patent's description of the invention*." *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1238 (Fed. Cir. 2014) (citation omitted) (emphasis added).

To the extent doubt remains, the extrinsic evidence shows that water is not a gelling agent and that a person of ordinary skill in the art would not understand it as such—the only conflicting evidence being the assumption underlying Dr. Bodmeier's opinion. One of the inventors, Masaru Tanjoh, was asked outright, "Water is not the gelling agent, correct?" Tanjoh Dep. 234:2-6, Dkt. 213-3. To which Mr. Tanjoh replied, "Correct." *Id.* at 234:6. "Have you ever heard of water being used as a gelling agent?" *Id.* at 234:7-8. Mr. Tanjoh: "No." *Id.* at 223:11. Although water is used in the process, Mr. Tanjoh acknowledged, consistent with the '180 patent's description, that water "is used in order to melt [dissolve] the solids." *Id.* at 89:6:12.

Even the literature references relied on by Dr. Bodmeier establish that water is not a gelling agent. The Sarkar article, as discussed above, for example, explains that HPMC has a tendency to gel on its own, and that when in an aqeuous solution, heat causes the water to get out of the HPMC's way so that it can do so. *See* Bodmeier Rep. ¶¶ 29-32, Dkt. 222-3 & Sarkar Article, Dkt. 222-3 at 195. The literature never refers to water as the "gelling agent," but rather merely explains the role of water in the thermogelation process. *See id.* Nothing in the literature suggests that a person or ordinary skill in the art would understand water to be a "gelling agent."

The only portion of the extrinsic evidence suggesting otherwise is Dr. Bodmeier's conclusory assumption underlying his opinion. A representative portion of Dr. Bodmeier's opinion states that "[a]lthough the literature I cite does not expressly refer to water as a 'gelling agent,' a POSA would understand that water is a gelling agent as described by these references because they disclose thermogelation processes in which water is a substance that increases the gelation of

HPMC." *See id.* ¶ 30. The literature on which Dr. Bodmeier relies, however, says nothing of the sort. The fact that water does *something* in the process, i.e., becomes disordered and allows HPMC to gel on its own, does not suggest that a person of ordinary skill in the art would recognize water as a "gelling agent," particularly when all the other evidence compels the contrary conclusion. Whether in the context of claim construction or summary judgment, conclusory expert testimony is not entitled weight. *See Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1050-55 (Fed. Cir. 2001).

The Court clarifies that "gelling agent" has its plain and ordinary meaning, which is a "substance that gels the film composition," but which cannot be water or heated water. This clarifying construction is based not only on the intrinsic record but also on factual findings from the extrinsic evidence, namely testimony by the experts and inventors and the scientific literature of record. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 842 (2015). Under the Court's clarifying construction, Mylan and Teva's accused products cannot, as a matter of law, be encompassed by the claims of the '180 patent because there is no dispute that the products do not contain any substance other than water that could be considered a "gelling agent." Because water does not qualify, Mylan and Teva are entitled to summary judgment.[7]

[7] In opposing summary judgment, Allergan repeatedly drew attention to the Court's "preliminary claim construction" chart, which the Court distributes in paper copy only to the parties in advance of claim construction hearings to help (1) inform the parties of the Court's preliminary thoughts and (2) focus the parties' argument. The preliminary chart defined the "gelling agent" as "a substance that increases gelation," but the preliminary chart is not an Order of the Court and is subject to change, as the parties were informed at the hearing. To extent the preliminary "gelling agent" construction conflicts with "a substance that gels the film composition," the preliminary construction is entitled to no weight (nor should it be considered because it is not a part of the record).

II. Alternate Disposition

While the Court sees the dispute regarding water as a matter for claim construction, the Court is mindful that this clarity results in part from the nature of Allergan's infringement theory as it developed on the summary judgment record. The Court therefore finds it appropriate, to avoid running afoul of claim construction principles, to evaluate the dispute as though it were a factual question, applying the summary judgment standard to the Court's original (unclarified) claim construction. The factual assessment is substantively identical to the resolution of the issue in terms of claim construction, but even if it exalts form over substance, the factual assessment is helpful in seeing the issue through a different lens.

The "gelling agent" must be a "substance that gels the film composition." *See* Dkt. 191 at 15. As the claims also require, the "gelling agent" must be *in* the "film composition" because the film composition comprises the gelling agent. *See* '180 patent at 6:38-46. The only "*substance*" "*in* the film composition" that could possibly gel the composition, according to Allergan's theory, is water. *See* Bodmeier Rep. ¶¶ 29-32, Dkt. 222-3. But there is no evidence in the record that would allow a fact finder to conclude that water "gels the film composition." In fact, the opposite conclusion is the only logical one because when HPMC is dissolved in water at room temperature, the water molecules form a cage-like structure around HPMC, *preventing* HPMC from gelling on its own. *See id.*, Dkt. 222-3 at 195 (Sarkar article).

Allergan's theory requires *heated* water—no expert opines that room temperature water can be a "gelling agent." Yet "heat" is not a "substance" in the film composition, and there is no evidence from which a fact finder could conclude otherwise. Allergan's position would suggest that any external influence, such as vibration, sound, etc., could qualify as a "substance that gels the film composition" as long as the external influence assisted or allowed HPMC to gel on its

own. This is simply not what the inventors of the '180 patent had in mind, and if it was, the inventors should not have recited a "gelling agent" in the claims. Allergen's theory effectively renders the "gelling agent" limitation meaningless.

Even if a person of ordinary skill in the art viewed heated water as a "gelling agent," as Dr. Bodmeier suggests, and heated water could logically be considered a "substance" in the film composition, there is no competent summary judgment evidence from which a fact finder could conclude that heated water "gels the film composition," as the Court's claim construction requires. *See* Dkt. 191 at 15. The substance that gels the film composition must be the thing that does the gelling. Water, or heated water, is not gelling anything. Rather, heat causes the water to become more disordered, thereby allowing HPMC to gel on its own. *See id.*, Dkt. 222-3 at 195 (Sarkar article).

The only evidence to the contrary is Dr. Bodmeier's conclusory assumption that because water is playing such a role during thermogelation, a person of ordinary skill in the art would recognize the water to be a gelling agent. *See* Bodmeier Rep. ¶¶ 29-32, Dkt. 222-3. But this expert testimony is not supported by, and even conflicts with, the evidence upon which it is based, and is thus nothing more than conclusory expert testimony. Such testimony is not sufficient to avoid summary judgment. *See Novartis*, 271 F.3d at 1050-55. In sum, even if viewed as a factual infringement question evaluated under the Court's original claim construction, a fact finder could not conclude that the water used to make the accused Vcaps Plus capsules is the "gelling agent."[8]

[8] The Court does not see it necessary to address Teva's alternate grounds for summary judgment, i.e., whether the accused product was formed from a film composition comprising a "gelling aid."

CONCLUSION

Because the '180 patent requires a "gelling agent," which is construed as a "substance that gels the film composition," but which cannot be water or heated water, Mylan and Teva cannot infringe the '180 patent as a matter of law. Alternatively, even if heated water could in theory be considered by a person of ordinary skill in the art to be a "gelling agent," there is no competent summary judgment evidence from which a fact finder could conclude that heated water "gels the film composition," as the Court's claim construction requires. Mylan and Teva have met their summary judgment burden.

Accordingly,

It is **RECOMMENDED**:[9]

(1) Teva and Mylan's motions for summary judgment, Dkts. 213 & 214, should be granted.

(2) Teva's motion for summary judgment of improper Orange Book listing, Dkt. 216, should be denied as moot.

(3) Having resolved all claims between the parties, the Court should enter final judgment in favor of Mylan and Teva.

SIGNED this 28th day of September, 2017.

ROY S. PAYNE
UNITED STATES MAGISTRATE JUDGE

[9] A party's failure to file written objections to the findings, conclusions, and recommendations contained in this report within fourteen days after being served with a copy shall bar that party from de novo review by the district judge of those findings, conclusions, and recommendations and, except on grounds of plain error, from appellate review of unobjected-to factual findings, and legal conclusions accepted and adopted by the district court. Fed. R. Civ. P. 72(b)(2); *see Douglass v. United Servs. Auto. Ass'n.*, 79 F.3d 1415, 1430 (5th Cir. 1996) (en banc).